

REMARKS

Claims 30-39 are pending in the application, are rejected, and are at issue. Claims 30-35 and 37-39 are rejected as anticipated by Muller et al. U.S. Patent No. 6,537,199. Claim 36 is rejected as obvious over Muller et al in view of Muller et al. U.S. Patent No. 6,547,715. Claim 30 is the only independent claim.

Applicant previously filed a request for pre-appeal brief review in response to a final action. The notice of panel decision maintained the rejection of the claims. A significant basis for the rejection relates to the meaning of the word "bioactive". The action stated that Muller et al. '199 "discloses that the jaws can be made of a bioactive ceramic material or silicone resin as admitted by the applicant." Ignoring the reference to jaws, there is no disclosure or suggestion that the attenuator in Muller et al. be of a ceramic material. Muller et al. only discloses silicone resin. The action otherwise suggests that because silicone can have a minor effect on living organism it is a bioactive substance. Applicants disagree. Filed herewith is a declaration under 37 CFR 1.132 which discuss relevant terms in the industry and refutes the suggestion that a silicone resin is understood to be a bioactive material.

Claim 30 specifies a self-crimping ossicular prosthesis comprising a pair of jaws of a bioactive material. Each jaw comprises a body having a semi-cylindrical inner surface for engaging opposite sides of an ossicle when implanted in a human ear, to anchor to the ossicle. A spring element of a flexible material, different from the pair of jaws, is operatively coupled to the

jaws for biasing the jaws toward one another to provide clamping pressure. An actuator element is operatively coupled to the spring element.

Muller et al. in Fig. 6, and as discussed at col. 9, lines 12-30, discloses a device for mechanical coupling of a driver to a coupling site of the ossicular chain. The device includes a coupling element 35 in the form of a U-shape spring clamp to partially surround a coupling site 16 of the ossicular chain. An attenuator 34 is disposed between the coupling element 35 and the coupling site 16 to protect against damage. The attenuator is indicated to be of an entropy-elastic or rubber-elastic material, preferably a silicone resin. The purpose of the attenuator is otherwise generally described at col. 5, lines 11-56.

Muller et al. does not disclose or suggest any jaw, let alone a pair of jaws. It discloses a single U-shaped clamping element. The element alleged in the action to engage the ossicular chain, the attenuator, is not of a bioactive material. A bioactive material would anchor to the ossicle. The attenuator is not intended to anchor to the ossicle. It is functional to provide a non-rigid connection to the ossicle. Nor is there a spring element operatively coupled to jaws for biasing jaws toward one another to provide clamping pressure. As such, there is no anticipation and the rejection is improper.

The final action, at page 2, references Muller et al. disclosing "a pair of jaws 34". Element 34 is a single element. It is not a pair of elements. It is formed as a piece of hose, i.e., cylindrical, which has been slit lengthwise. It is a single, cylindrical element. It is in the nature of a cylindrical sleeve with a slit to allow it to be placed surrounding part of the ossicular chain. The final action, at page 4, states that the upper and lower halves of element 34 comprise a pair of jaws.

However, these are not distinct elements. To make them distinct elements would require slitting the attenuator to have two semi-cylindrical halves. Doing so would result in an inoperative device as it would not be self-retaining on the coupling site, as intended. As such, the claim limitation to a pair of jaws is not met by the reference and there is clear error in the rejection.

Claim 30 specifies that the jaws are of a bioactive material. A bioactive material is a material which chemically interacts with the surrounding tissue in such a manner to promote a specific type of tissue response, as described in the declaration. The attenuator of Muller et al. is formed of an elastic silicone material. To perform its function the attenuator must retain its elastic properties. For example, column 5, lines 44-48, discuss non-rigidity or pliability of the attenuator. If the silicone chemically interacts with the surrounding tissue, i.e., the incus bone, then it would form a bond which would cause the attenuator to be rigid and non-pliable. This renders the device non-elastic in nature so that the attenuator would not function for its intended purpose.

There is no disclosure in Muller et al. that the attenuator is formed of a bioactive material. Nor does the action reference any disclosure in Muller et al. Thus, not only does Muller et al. fail to disclose the use of a bioactive material for the attenuator, it teaches away from the use of a bioactive material as use of a bioactive material will be contrary to the functional requirements of an attenuator.

Moreover, the final action in the paragraph bridging pages 4 and 5 states that Muller “discloses that the jaws can be made of a bioactive ceramic material or silicone resin as admitted by the applicant”. There has been no such admission by applicant. Nor does Muller et al. teach that

the attenuator can be made of a ceramic material. A ceramic material is not elastic in nature. As such, the limitation to jaws being of a bioactive material is not met by Muller et al.

Finally, Muller et al. does not disclose or suggest a spring element of a flexible material, different from a pair of jaws, operatively coupled to jaws for biasing the jaws towards one another to provide clamping pressure. If any element in Muller et al. corresponds to a pair of jaws it is the spring arms 36. However, the spring arms 36 are integral elements of the coupling element 35. There is no spring element of a different material to bias the spring clamps toward one another. The coupling element 35 comprises a unitary spring arm. It is pushed onto the attenuator to mount to the ossicular chain.

Because Muller et al. did not disclose each and every element of Claim 30, arranged as in the claim, there is no anticipation and the rejection is improper. Moreover, because Muller et al. does not suggest the claimed invention and, in fact, teaches away from the claimed invention, any obviousness rejection would also be improper.

Claims 31-35 and 37-39 depend from Claim 30 and are likewise not anticipated. Additionally, Claim 34 specifies the spring element has opposite ends each received in an opening in one of the jaws to provide swivel joints. There is no such structure disclosed or suggested in Muller et al. Claim 34 is believed allowable for this reason as well.

Claim 35 depends from Claim 34 and specifies that the swivel joint is surrounded by an elastomer. While Muller et al. uses an elastic material for an attenuator, it does not use any such material to surround a swivel joint.

The action references Fig. 10 of Muller et al. as a swivel joint. Muller et al. provides no such teaching. The action states that "the spring element 35 has opposite ends each received in an opening (slit) in one of the jaws to provide swivel joints that may further be surrounded by an elastomer (Figs. 26-29)". Initially, there is no jaw, let alone "one of the jaws". The slit is in a cylindrical sleeve, the opposite ends of the coupling element are not received in the slit. There is no joint, let alone a swivel joint between the same. Moreover, it is not apparent how this structure would be surrounded by an elastomer or for what purpose. This is an improper hindsight interpretation of the reference based on applicants claim language.

The action indicates that end of the spring 36 fits in a groove 35 on a coupler 34. Element 34 is the attenuator. Element 35 is a coupling element. It is not a groove. The spring arms are part of the coupling element 35. There is no swiveling. The reference to Figs. 26-29 is not understood as these relate to entirely different embodiments. While Figs. 26-29 describe a ball joint, it is for the rod connection to a coupling element and not a spring element connecting to a jaw.

For the above reasons, Claims 30-35 and 37-39 are believed allowable and withdrawn with the rejections requested.

Applicant traverses the rejection of Claim 36 as obvious over the Muller et al. '199 Patent and further in view of Muller et al. U.S. Patent No. 6,547,715.

Claim 36 depends from Claim 30 and further specifies a spacer to temporarily hold the jaws in an open position until implantation in a human ear is completed. The deficiencies with respect to the Muller et al. '199 Patent and independent Claim 30 are discussed above. The Muller et al. '715 Patent does not disclose or suggest these deficiencies. Therefore, no combination of the

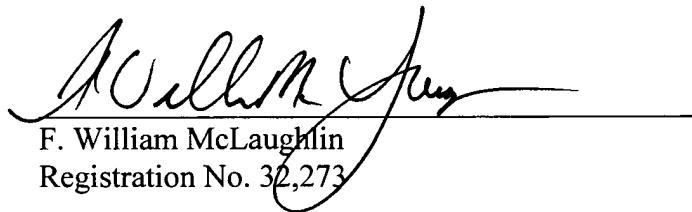
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references results in the claimed invention. Nor does it suggest the claimed invention. Therefore,

Claim 36 is not obvious over this combination and the rejection ought be withdrawn.

Reconsideration of the application and allowance and passage to issue are requested.

Respectfully submitted,



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